IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,)
Plaintiff,)
v.) C.A. No. 08-112 (SLR)
BARR LABORATORIES, INC.,)
Defendant.)
BARR LABORATORIES, INC.,)
Counterclaim-Plaintiff,)
v.)
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,))
Counterclaim-Defendant.)

REPLY TO COUNTERCLAIMS

Plaintiff/Counterclaim-Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), for its reply to the counterclaims of Defendant/Counterclaim-Plaintiff Barr Laboratories, Inc. ("Barr Labs"), in its "Amended Answer and Counterclaim to Complaint," dated March 19, 2008, avers as follows:

PARTIES

- 1. Upon information and belief, GSK admits the allegations of paragraph 1.
- 2. GSK admits the allegations of paragraph 2.

JURISDICTION AND VENUE

- 3. GSK denies the allegations of paragraph 3, except admits that Barr Labs purports to bring an "action aris[ing] under the patents laws of the United States of America", and that Barr Labs purports to base jurisdiction on 28 U.S.C. §§ 1331, 1338(a), 2201 and/or 2202.
 - 4. GSK admits the allegations of paragraph 4.
 - 5. GSK admits the allegations of paragraph 5.

BACKGROUND

- 6. GSK admits the allegations of paragraph 6, and adds that each Patent-in-Suit was assigned to SmithKline Beecham Corporation in 2001.
 - 7. GSK admits the allegations of paragraph 7.
 - 8. GSK admits the allegations of paragraph 8.
 - 9. GSK admits the allegations of paragraph 9.
 - 10. GSK admits the allegations of paragraph 10.
 - 11. GSK admits the allegations of paragraph 11.
 - 12. GSK admits the allegations of paragraph 12.
 - 13. GSK admits the allegations of paragraph 13.
 - 14. GSK admits the allegations of paragraph 14.
- 15. GSK admits the allegations of paragraph 15, except refers to the entry for NDA 21-319 and Avodart in the "Orange Book" for its contents.
- 16. GSK admits the allegations of paragraph 16, except refers to Barr Labs' ANDA for its contents.

- 17. GSK denies the allegations of paragraph 17, except states that it received a letter from Barr Labs, dated January 11, 2008, which purported to set forth the alleged factual and legal basis for Barr Labs' Paragraph IV certification to the FDA. GSK refers to that letter for its contents.
 - 18. GSK admits the allegations of paragraph 18.
 - 19. GSK admits the allegations of paragraph 19.
- 20. GSK admits the allegations of paragraph 20 (see Complaint, Prayer for Relief "D"), except denies that Barr Labs is entitled to any relief under 35 U.S.C. § 285.

COUNT I <u>Declaration of Non-Infringement of the Patents-in-Suit</u>

- 21. GSK incorporates by reference its replies to paragraphs 1 through 20 as if fully set forth herein.
- 22. GSK denies the allegations of paragraph 22, except admits that Barr Labs purports to seek a declaration that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, or sale of Barr Labs' ANDA product.
 - 23. GSK admits the allegations of paragraph 23.
 - 24. GSK denies the allegations of paragraph 24.
 - 25. Paragraph 25 states a legal conclusion to which no response is required.
 - 26. GSK denies the allegations of paragraph 26.

COUNT II Declaration of Invalidity of the Patents-in-Suit

27. GSK incorporates by reference its replies to paragraphs 1 through 26 as if fully set forth herein.

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- 28. GSK denies the allegations of paragraph 28, except admits that Barr Labs purports to seek a declaration that the Patents-in-Suit are invalid.
 - 29. GSK admits the allegations of paragraph 29.
 - 30. GSK denies the allegations of paragraph 30.
 - 31. Paragraph 31 states a legal conclusion to which no response is required.
 - 32. GSK denies the allegations of paragraph 32.

GSK states that the final paragraph contains a request for relief for which no response is required. To the extent that one is required, GSK denies that Barr Labs is entitled to such relief.

GSK reiterates that this case is exceptional within the meaning of 35 U.S.C. § 285. (See Complaint, Prayer for Relief "D".)

GSK denies that Barr Labs is entitled to a trial by jury.

GSK denies all allegations not expressly denied or otherwise responded to herein.

AFFIRMATIVE DEFENSES

GSK asserts the following affirmative and other defenses. In asserting these defenses, GSK does not assume the burden of proof with respect to any issue upon which applicable law places the burden of proof upon Barr Labs.

First Affirmative Defense

Barr Labs' counterclaims, in whole or in part, fail to state claims upon which relief can be granted.

Second Affirmative Defense

Barr Labs' counterclaims, in whole or in part, are not justiciable.

Third Affirmative Defense

GSK has not knowingly or intentionally waived any applicable affirmative defenses and reserves the right to assert and rely upon such other affirmative defenses as may become available or apparent during discovery proceedings. GSK further reserves the right to amend its Reply and/or its affirmative defenses accordingly, and/or to delete affirmative defenses that GSK determines during the course of subsequent discovery are not applicable.

WHEREFORE, GSK respectfully requests that this Court enter judgment:

- (i) dismissing Barr Labs' counterclaims in their entirety with prejudice and
- (ii) granting such other further relief as this Court deems just and proper.

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April 10, 2008

CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

John C. Phillips, Jr., Esquire Brian E. Farnan, Esquire PHILLIPS, GOLDMAN & SPENCE, P.A.

I further certify that I caused to be served copies of the foregoing document on

April 10, 2008 upon the following in the manner indicated:

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